INTERNATIONAL STANDARD

ISO 80601-2-70

First edition
2015-01-15

Medical electrical equipment —

Part 2-70:
Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment

Appareils électromédicaux —

Partie 2-70: Exigences particulières pour la sécurité de base et les performances essentielles de l'équipement de thérapie respiratoire pour l'apnée du sommeil

Reference number
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Contents

Page

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/IEC 80601-2-70 was prepared by a joint working group of Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment* and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC D, *Electrical equipment*.

This first edition of ISO 80601-2-70 cancels and replaces the second edition of ISO 17510-1:2007. This edition of ISO 80601-2-70 constitutes a technical revision of ISO 17510-1:2007 and includes an alignment with third edition of IEC 60601-1 and IEC 60601-1-11.

The most significant changes are the following modifications:

— identification of ESSENTIAL PERFORMANCE for SLEEP APNOEA BREATHING THERAPY EQUIPMENT and its ACCESSORIES;

and the following additions:

— tests for therapy performance; and

— new symbols.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

— Requirements and definitions: roman type.

— *Test specifications: italic type.*

— Informative material appearing outside of tables, such as notes, examples and references: smaller type. Normative text of tables is also in a smaller type.

— TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS TYPE.

In referring to the structure of this standard, the term

— "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

— "subclause" means a numbered subdivision of a clause (e.g. 201.7.1, 201.7.2 and 201.7.2.1 are all subclauses of Clause 201.7).

References to clauses within this standard are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

— "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;

— "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

— "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

The attention of Member Bodies and National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised ISO or IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication not be adopted for mandatory implementation nationally earlier than 3 years from the date of publication for equipment newly designed and not earlier than 5 years from the date of publication for equipment already in production.

Introduction

Sleep apnoea is a chronic medical condition where the PATIENT repeatedly stops breathing during sleep. These episodes typically last 10 s or more and cause the oxygen levels in the blood to drop. It can be caused by obstruction of the upper airway (obstructive sleep apnoea or OSA) or by a failure of the brain to initiate a breath (central sleep apnoea).

NOTE SLEEP APNOEA BREATHING THERAPY EQUIPMENT is intended for the treatment of obstructive sleep apnoea and not central sleep apnoea.

Sleep apnoea, if untreated, can cause and worsen other medical conditions, including hypertension, heart failure and diabetes[1].

Hypopnoea refers to a transient reduction of airflow, often while the PATIENT is asleep, that lasts for at least 10 s, shallow breathing, or an abnormally low respiratory rate. Hypopnoea is less severe than apnoea. It also results in decreased air movement into the lungs and can cause oxygen levels in the blood to drop. It is commonly due to partial obstruction of the upper airway. [16] [2]

Awareness of the RISKS associated with sleep apnoea has grown significantly. As a result, the use of SLEEP APNOEA BREATHING THERAPY EQUIPMENT to treat both sleep apnoea and hypopnoea has become common.

This document covers BASIC SAFETY and ESSENTIAL PERFORMANCE requirements needed to protect PATIENTS in the use of this ME EQUIPMENT.

ISO 80601-2-70 covers SLEEP APNOEA BREATHING THERAPY EQUIPMENT for PATIENT use. ISO 17510 applies to MASKS and ACCESSORIES used to connect SLEEP APNOEA BREATHING THERAPY EQUIPMENT to the PATIENT. Figure AA.1 shows this diagrammatically.

[1] source: http://sleepdisorders.about.com/od/glossary/g/Sleep_Apnea.htm

[2] Figures in square brackets refer to the Bibliography.

Medical Electrical Equipment —

Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment

201.1 Scope, object and related standards

IEC 60601-1:2005+A1:2012, Clause 1 applies, except as follows:

201.1.1 * Scope

IEC 60601-1:2005+A1:2012, 1.1 is replaced by:

This particular standard is applicable to the BASIC SAFETY and ESSENTIAL PERFORMANCE of SLEEP APNOEA BREATHING THERAPY EQUIPMENT, hereafter referred to as ME EQUIPMENT, intended to alleviate the symptoms of PATIENTS who suffer from obstructive sleep apnoea by delivering a therapeutic breathing pressure to the respiratory tract of the PATIENT. SLEEP APNOEA BREATHING THERAPY EQUIPMENT is intended for use in the HOME HEALTHCARE ENVIRONMENT by LAY OPERATORS as well as in professional healthcare institutions.

This particular standard excludes SLEEP APNOEA BREATHING THERAPY EQUIPMENT intended for use with neonates.

This particular standard is applicable to ME EQUIPMENT or an ME SYSTEM intended for those PATIENTS who are not dependent on mechanical ventilation.

This particular standard is not applicable to ME EQUIPMENT or an ME SYSTEM intended for those PATIENTS who are dependent on mechanical ventilation such as PATIENTS with central sleep apnoea.

This particular standard is also applicable to those ACCESSORIES intended by their MANUFACTURER to be connected to SLEEP APNOEA BREATHING THERAPY EQUIPMENT, where the characteristics of those ACCESSORIES can affect the BASIC SAFETY or ESSENTIAL PERFORMANCE of the SLEEP APNOEA BREATHING THERAPY EQUIPMENT.

MASKS and application ACCESSORIES intended for use during sleep apnoea breathing therapy are additionally addressed by ISO 17510. [3] Refer to Figure AA.1 for items covered further under this standard.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of the general standard.

NOTE 4 See also 4.2 of the General Standard.

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3) To be published.

This particular standard is not applicable to high-frequency jet ventilators (HFJVs) or high-frequency oscillatory ventilators (HFOVs).[16]

This particular standard does not specify the requirements for ventilators or ACCESSORIES intended for critical care ventilators for ventilator-dependent PATIENTS which are given in ISO 80601-2-12.

This particular standard does not specify the requirements for ventilators or ACCESSORIES intended for anaesthetic applications which are given in IEC 80601-2-13.

This particular standard does not specify the requirements for ventilators or ACCESSORIES intended for home care ventilators for ventilator-dependent PATIENTS which are given in ISO 10651-2[4)].

This particular standard does not specify the requirements for ventilators or ACCESSORIES intended for emergency and transport which are given in ISO 10651-3[5)].

This particular standard does not specify the requirements for ventilators or ACCESSORIES intended for home-care ventilatory support devices which are given in ISO 10651-6[6)].

This particular standard is a particular standard in the IEC 60601-1 and ISO/IEC 80601 series of standards.

201.1.2 Object

IEC 60601-1:2005, 1.2 is replaced by:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for SLEEP APNOEA BREATHING THERAPY EQUIPMENT [as defined in 201.3.212].

201.1.3 Collateral standards

IEC 60601-1:2005+A1:2012, 1.3 applies with the following addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and 201.2 of this particular standard.

IEC 60601-1-3:2008 does not apply.

201.1.4 Particular standards

IEC 60601-1:2005+A1:2012, 1.4 is replaced by:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard, including the collateral standards, as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY or ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard or the collateral standards.

For brevity, IEC 60601-1:2005+A 1:2012 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

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4) In the future, this standard is expected to be harmonized with the IEC 60601-1:2005 and IEC 60601-1-11:2010 at which time it will be replaced by ISO 80601-2-xx.

5) In the future, this standard is expected to be harmonized with the IEC 60601-1:2005 at which time it will be replaced by ISO 80601-2-xx.

6) In the future, this standard is expected to be harmonized with the IEC 60601-1:2005 and IEC 60601-1-11:2010 at which time it will be replaced by ISO 80601-2-xx.

The numbering of clauses and subclauses of this particular standard corresponds to those of the general standard with the prefix “201” (e.g. 201.1 in this particular standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “2xx” where xx is the final digits of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 208.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-8 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses or figures that are additional to those of the general standard are numbered starting from 201.101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses or figures that are additional to those of a collateral standard are numbered starting from 2xx, where “xx” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 211 for IEC 60601-1-11, etc.

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the section, clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

The following referenced documents are indispensable for the application of this document. The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE Informative references are listed in the Bibliography beginning on page 41.

IEC 60601-1:2005+A1:2012, Clause 2 applies, except as follows:

Replacement:

IEC 60601-1-2:2014, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic compatibility – Requirements and tests*

IEC 60601-1-3:2008, *Medical electrical equipment — Part 1-3: General requirements for basic safety and essential performance — Collateral Standard: Radiation protection in diagnostic X-ray equipment*

IEC 60601-1-6:2010, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability*
+Amendment 1:2013

IEC 60601-1-8:2006, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*
+Amendment 1:2012

IEC 60601-1-11:—[7] (Ed 2), *Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

IEC 61672-1:2013, *Electroacoustics — Sound level meters — Part 1: Specifications*

Addition:

ISO 3744:2010, *Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Engineering methods for an essentially free field over a reflecting plane*

ISO 4135:2001, *Anaesthetic and respiratory equipment — Vocabulary*

ISO 4871:1996, *Acoustics — Declaration and verification of noise emission values of machinery and equipment*

ISO 5356-1:2004, *Anaesthetic and respiratory equipment — Conical connectors — Cones and sockets*

ISO 7000:2012, *Graphical symbols for use on equipment — Registered symbols*

ISO 8185:2007[8], Humidifiers for medical use — General requirements for humidification systems

ISO 15223-1:2012, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

EN 15986:2011, *Symbol for use in the labelling of medical devices — Requirements for labelling of medical devices containing phthalates*

ISO 17510:—[9], *Sleep apnoea breathing therapy masks and application accessories*

ISO 23328-1:2003, *Breathing system filters for anaesthetic and respiratory use — Part 1: Salt test method to assess filtration performance*

ISO 23328-2:2002, *Breathing system filters for anaesthetic and respiratory use — Part 2: Non-filtration aspects*

IEC 60601-1:2005, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*
Amendment 1:2012

IEC 62366:2007, *Medical devices — Application of usability engineering to medical devices*
+Amendment 1:2014

ISO 80369-1:2010, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

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[7] To be published.

[8] In the future, this standard is expected to be harmonized with the IEC 60601-1:2005+A1:2012 and IEC 60601-1-11:2010 at which time it will be replaced by ISO 80601-2-74.

[9] To be published.

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 8185:2007, ISO 23328-2:2002, IEC 60601-1:2005+A1:2012, IEC 60601-1-2:2014, IEC 60601-1-6:2010+A1:2013, IEC 62366:2007+A1:2014, ISO 4135:2001 and the following apply.

NOTE An index of defined terms is found beginning on page 43.

Addition:

201.3.201
AIRWAY PRESSURE
P_{aw}
pressure at the PATIENT-CONNECTION PORT

201.3.202
AIRWAY PRESSURE ACCURACY
degree of correspondence between the pressure set on the SLEEP APNOEA BREATHING THERAPY EQUIPMENT and the actual (true) AIRWAY PRESSURE

201.3.203
BI-LEVEL PAP
BI-LEVEL POSITIVE AIRWAY PRESSURE
two therapeutic positive pressure levels at the PATIENT-CONNECTION PORT during the respiratory cycle

201.3.204
BREATHING GAS PATHWAY
pathway through which gas flows at respiratory pressures between the gas INTAKE PORT and the PATIENT-CONNECTION PORT

201.3.205
CPAP
CONTINUOUS POSITIVE AIRWAY PRESSURE
therapeutic CONTINUOUS POSITIVE AIRWAY PRESSURE during the respiratory cycle

201.3.206
FLOW-DIRECTION-SENSITIVE COMPONENT
component or ACCESSORY through which gas flow has to be in one direction only for proper functioning or PATIENT safety

[SOURCE: ISO 4135:2001, definitions 3.1.7, modified–Added ‘or ACCESSORY’ and replaced ‘must’ with ‘has to’.]

201.3.207
INTAKE PORT
port through which gas is drawn by SLEEP APNOEA BREATHING THERAPY EQUIPMENT

[SOURCE: ISO 4135:2001, definitions 3.2.11, modified–Replaced a ventilator or by a PATIENT with SLEEP APNOEA BREATHING THERAPY EQUIPMENT.]

201.3.208
MAXIMUM LIMITED PRESSURE
$P_{LIM\,\mathrm{max}}$
highest AIRWAY PRESSURE during NORMAL USE or under SINGLE FAULT CONDITION

201.3.209
MONITORING EQUIPMENT
ME EQUIPMENT or part that continuously or continually measures and continuously or continually or on OPERATOR-demand indicates the value of a variable to the OPERATOR

201.3.210
PROTECTION DEVICE
part or function of ME EQUIPMENT that, without intervention by the OPERATOR, protects the PATIENT from hazardous output due to incorrect delivery of energy or substances

201.3.211
SELF-ADJUSTING
automatically adjusting the pressure in the BREATHING GAS PATHWAY according to the PATIENT'S needs during use

201.3.212
SLEEP APNOEA BREATHING THERAPY EQUIPMENT
ME EQUIPMENT intended to alleviate the symptoms of a PATIENT who suffers from sleep apnoea by delivering a therapeutic breathing pressure to the PATIENT

Note 1 to entry: SLEEP APNOEA BREATHING THERAPY EQUIPMENT is primarily used in the HOME HEALTHCARE ENVIRONMENT by a LAY OPERATOR without direct professional supervision.

201.4 General requirements

IEC 60601-1:2005+A1:2012, Clause 4 applies, except as follows:

201.4.3 ESSENTIAL PERFORMANCE

IEC 60601-1:2005+A1:2012, 4.3 applies, except as follows:

Additional subclause:

201.4.3.101 * Additional requirements for ESSENTIAL PERFORMANCE

For the purposes of this standard, SLEEP APNOEA BREATHING THERAPY EQUIPMENT is considered to not have ESSENTIAL PERFORMANCE. Notwithstanding this fact, when this standard refers to ESSENTIAL PERFORMANCE as acceptance criteria, the static pressure shall be evaluated. The method of subclause 202.6.2.1.10 may be used to evaluate static pressure as an acceptance criterion following specific tests required by this standard.

201.4.6 * ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT

Amendment (add at end of 4.6 prior to the compliance check):

The BREATHING GAS PATHWAY, its parts and ACCESSORIES shall be subject to the requirements for APPLIED PARTS according to subclause 201.11.6.4. The SLEEP APNOEA BREATHING THERAPY EQUIPMENT parts or ACCESSORIES that can come into contact with the PATIENT shall be subject to the requirements for APPLIED PARTS according to this subclause.

NOTE The ACCESSORIES that can come into contact with the PATIENT also are subject to ISO 17510:—.

201.5 General requirements for testing of ME EQUIPMENT

IEC 60601-1:2005+A1:2012, Clause 5 applies, except as follows:

Addition:

201.5.101 Additional requirements for general requirements for testing of ME EQUIPMENT

201.5.101.1 Gas flowrate and pressure specifications

In this standard, requirements for the flowrate and pressure are expressed as if tested under STPD (standard temperature and pressure dry) conditions.

NOTE For the purposes of this standard, STPD is 101,3 kPa at an operating temperature of 20 °C, dry.

Correct all test measurements to STPD, as appropriate.

201.5.101.2 * SLEEP APNOEA BREATHING THERAPY EQUIPMENT testing errors

For the purposes of this standard, tolerances declared in the ACCOMPANYING DOCUMENTS shall include the uncertainty of the measurement used to determine the specification.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005+A1:2012, Clause 6 applies.

201.7 ME EQUIPMENT identification, marking and documents

IEC 60601-1:2005+A1:2012, Clause 7 applies, except as follows:

201.7.1.2 * Legibility of markings

IEC 60601-1:2005+A1:2012, 7.1.2 applies, except as follows:

Replacement (at the end of the second sentence of the second paragraph of the compliance check):

Replace ‘1 m’ with ‘0,5 m’

Additional subclauses:

201.7.2.4.101 Additional requirements for ACCESSORIES

ACCESSORIES supplied separately shall fulfil the requirements of 201.7.2.101 and shall be marked with an indication of any limitations or adverse effects of the ACCESSORY on the BASIC SAFETY of the SLEEP APNOEA BREATHING THERAPY EQUIPMENT, if applicable. If marking the ACCESSORY is not practicable, this information may be placed in the instructions for use.

Check compliance by inspection and inspection of the RISK MANAGEMENT FILE for any limitations or adverse effects of the ACCESSORY.

201.7.2.13.101 Additional requirements for physiological effects

All natural rubber latex-containing components in the BREATHING GAS PATHWAYS or ACCESSORIES shall be marked as containing latex. Such marking shall be CLEARLY LEGIBLE. Symbol 5.4.5 from ISO 15223-1:2012, (Table 201.D.1.101, symbol 4) may be used. The instructions for use shall disclose all natural rubber latex-containing components.

Check compliance by inspection.

201.7.2.17.101 Additional requirements for protective packaging

Packages shall be CLEARLY LEGIBLE and shall be marked as follows:

— with a description of the contents;

— with an identification reference to the batch, type or serial number or one of symbol 5.1.5, symbol 5.1.6 or symbol 5.1.7 from ISO 15223-1:2012 (Table 201.D.1.101, symbol 1, symbol 2 or symbol 3);

— with, for packages containing natural rubber latex, the word "LATEX", or symbol 5.4.5 from ISO 15223-1:2012 (Table 201.D.1.101, symbol 4).

Check compliance by inspection.

201.7.2.101 Additional requirements for marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

The marking of SLEEP APNOEA BREATHING THERAPY EQUIPMENT, parts or ACCESSORIES shall be CLEARLY LEGIBLE and shall include the following:

a) any particular storage and/or handling instructions;

b) any particular warnings and/or precautions relevant to the immediate operation of the SLEEP APNOEA BREATHING THERAPY EQUIPMENT;

If applicable, the marking of OPERATOR-accessible SLEEP APNOEA BREATHING THERAPY EQUIPMENT, parts or ACCESSORIES shall be CLEARLY LEGIBLE and shall include the following, unless the size of ME EQUIPMENT, parts or ACCESSORY, or the nature of its ENCLOSURE, does not allow affixation of these markings in which case the remaining markings shall be recorded in the instructions for use,

c) an arrow indicating the direction of the flow for FLOW-DIRECTION-SENSITIVE COMPONENTS that are OPERATOR-removable without the use of a TOOL;

d) a caution not to obstruct the gas INTAKE PORT;

EXAMPLE Caution: Gas Intake – Do not obstruct

e) an indication as to whether use of an appropriate BREATHING SYSTEM FILTER is required;

f) if required, the cleaning or replacement interval of the BREATHING SYSTEM FILTER;

g) an indication as to whether the use of an appropriate air intake filter is required;

h) if required, the cleaning or the replacement interval of the air intake filter.

Check compliance by inspection.

201.7.4.3 Units of measurement

IEC 60601-1:2005+A1:2012, 7.4.3 applies, except as follows:

Amendment (add to the bottom as a new row in Table 1):

All gas volume, flow and leakage specifications shall be expressed at STPD (standard temperature and pressure, dry).

NOTE For the purposes of this standard, STPD is 101,3 kPa at an operating temperature of 20 °C, dry.

201.7.9.1 * Additional general requirements

IEC 60601-1:2005+A1:2012, 7.9.1 applies, except as follows:

Amendment (replace the first dash with):

— name or trade name and address of

  — the MANUFACTURER; and

  — where the MANUFACTURER does not have an address within the locale, an authorized representative within the locale,

to which the RESPONSIBLE ORGANIZATION can refer;

201.7.9.2 Instructions for use

IEC 60601-1:2005+A1:2012, 7.9.2 applies, except as follows:

Additional subclauses:

201.7.9.2.1.101 Additional general requirements

The instructions for use shall disclose the following:

a) if the SLEEP APNOEA BREATHING THERAPY EQUIPMENT, its parts or ACCESSORIES are intended for single use, information on known characteristics and technical factors known to the MANUFACTURER that could pose a RISK if the SLEEP APNOEA BREATHING THERAPY EQUIPMENT, its parts or ACCESSORIES would be reused.

Check compliance by inspection of the instructions for use.

201.7.9.2.2.101 Additional requirements for warnings and safety notices

The instructions for use shall include

a) a caution statement to the effect that "CAUTION: The equipment must not be covered or positioned in such a way that the operation or performance of the equipment is adversely affected". The caution shall be accompanied by applicable examples.

   EXAMPLE 1 Do not position next to a curtain that blocks the flow of cooling air, thereby causing the equipment to overheat.

   EXAMPLE 2 Do not block the gas INTAKE PORT, thereby interfering with therapy.

b) unless the SLEEP APNOEA BREATHING THERAPY EQUIPMENT is intended for use with an oxygen concentration above ambient, a warning to the effect that "WARNING: Sources of oxygen must be located more than 1 m from the equipment to avoid the risk of fire and burns."

c) a warning statement to the effect that "WARNING: Nebulisation or humidification can increase the resistance of breathing system filters and the operator must monitor the breathing system filter frequently for increased resistance and blockage to ensure the delivery of the therapeutic pressure."

Unless not applicable, the instructions for use shall include the following:

d) a warning to the effect that "WARNING: Failure to use a mask or accessory that minimizes rebreathing of carbon dioxide or permits spontaneous breathing can cause asphyxiation."

Check compliance by inspection of the instructions for use.

201.7.9.2.5.101 Additional requirements for ME EQUIPMENT description

The instructions for use shall include

a) a statement to the effect that the patient should use the therapeutic pressure setting, as individually determined with the configuration of the equipment and accessories, being used.

b) a statement to the effect that the proper placement and positioning of the patient interface is critical to the consistent operation of this equipment.

EXAMPLE The proper placement and positioning of the MASK on the face is critical to the consistent operation of this equipment.

Check compliance by inspection of the instructions for use.

201.7.9.2.9.101 Additional requirements for operating instructions

The instructions for use shall include an explanation of the meaning of the IP classification marked on the ME EQUIPMENT.

If applicable, the instructions for use shall include the procedure necessary to determine the state of the INTERNAL ELECTRICAL POWER SOURCE.

Check compliance by inspection of the instructions for use.

201.7.9.2.14.101 Additional requirements for ACCESSORIES, supplementary equipment, used material

If applicable, the instructions for use shall disclose

a) any restrictions on the positioning of components within the BREATHING GAS PATHWAY.

EXAMPLE 1 Where such components are FLOW-DIRECTION-SENSITIVE COMPONENTS.

b) a diagram of the SLEEP APNOEA BREATHING THERAPY EQUIPMENT, including a diagram for OPERATOR-detachable parts of the BREATHING GAS PATHWAY either supplied or recommended in the instructions for use.

c) details of any restrictions on the sequence of components within the BREATHING GAS PATHWAY.

EXAMPLE Proper location of FLOW-DIRECTION SENSITIVE COMPONENTS.

d) for the gas INTAKE PORT filter, the maximum duration of use and the details on how to replace this filter.

e) the specification of the BREATHING SYSTEM FILTER including, but not limited to, the volume, the compliance, the resistance over the flow range, the maximum duration of use and the details on how to replace this filter.

Check compliance by inspection of the instructions for use and inspection of the RISK MANAGEMENT FILE for any adverse effect of any recommended ACCESSORY.

201.7.9.3.1.101 * Additional general requirements

The technical description shall disclose

a) a pneumatic diagram of the SLEEP APNOEA BREATHING THERAPY EQUIPMENT, including a diagram for OPERATOR-detachable parts of the BREATHING GAS PATHWAY either supplied or recommended in the instructions for use.

b) a listing of the following pressures:

— MAXIMUM LIMITED PRESSURE ($P_{LIM\,max}$);

— if adjustable, the RATED range of the set AIRWAY PRESSURE during NORMAL USE;

NOTE There can be more than one set AIRWAY PRESSURE.

c) a statement to the effect that the RESPONSIBLE ORGANIZATION

— should ensure the compatibility of the equipment and all of the parts and accessories used to connect to the patient before use;

— should ensure that the therapeutic pressure settings were determined for the patient individually with the configuration of the equipment to be used, including accessories; and

— should periodically reassess the setting(s) of the therapy for effectiveness; and

d) the specification of the gas INTAKE PORT filter including, but not limited to the most penetrating particle size and the penetration value for that particle size.

If applicable, the technical description shall disclose

e) for ME EQUIPMENT without a respiratory pressure-measuring device, the stability of pressure control between recommended maintenance times.

f) the means of alternating between levels in BI-LEVEL POSITIVE AIRWAY PRESSURE mode.

g) a description of the comfort features (e.g. automatic start / stop functions, fall-to-sleep ramps, automatic inspiratory pressure increase or automatic expiratory pressure decrease) and their range of adjustment.

h) a statement to the effect that combinations with medical devices other than recommended can alter the performance of the equipment (e.g. combinations with a HUMIDIFIER, filter, BREATHING SYSTEM FILTER, or EXHAUST PORT).

Check compliance by inspection of the technical description.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

IEC 60601-1:2005+A1:2012, Clause 8 applies.

201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005+A1:2012, Clause 9 applies, except as follows:

Additional subclauses:

201.9.6.2.1.101 * Additional requirements for audible acoustic energy

The A-weighted sound pressure level emitted by the SLEEP APNOEA BREATHING THERAPY EQUIPMENT shall be measured in accordance with ISO 4871:1996 and ISO 3744:2010 using engineering method grade 2 and disclosed in the instructions for use. The A-weighted sound power level shall be calculated according to 8.1 of ISO 3744:2010 and disclosed in the instructions for use.

Check compliance with the following test:

a) *Place the* SLEEP APNOEA BREATHING THERAPY EQUIPMENT *on a sound-reflecting plane and attach the least favourable* BREATHING GAS PATHWAY *from those indicated in the instructions for use.*

NOTE The least favourable BREATHING GAS PATHWAY *configuration can vary by mode, as applicable.*

b) *If a* HUMIDIFIER *is provided with or specified in the* ACCOMPANYING DOCUMENTS *of the* SLEEP APNOEA BREATHING THERAPY EQUIPMENT, *include the* HUMIDIFIER *in the test. Fill the* HUMIDIFIER *to the least favourable level.*

c) *Connect the standard resistance, 40 mm length and outlet angle of 45° (as indicated in Figure 201.101) to the* PATIENT-CONNECTION PORT.

d) *Acoustically isolate the* BREATHING TUBES *and the gas leaving at the resistance placed at the* PATIENT-CONNECTION PORT *by a suitable means out of the testing area so that the noise caused by the* BREATHING TUBE *and the gas flow does not interfere with the sound measurement of the* SLEEP APNOEA BREATHING THERAPY EQUIPMENT.

NOTE The internal diameter is 4 mm.

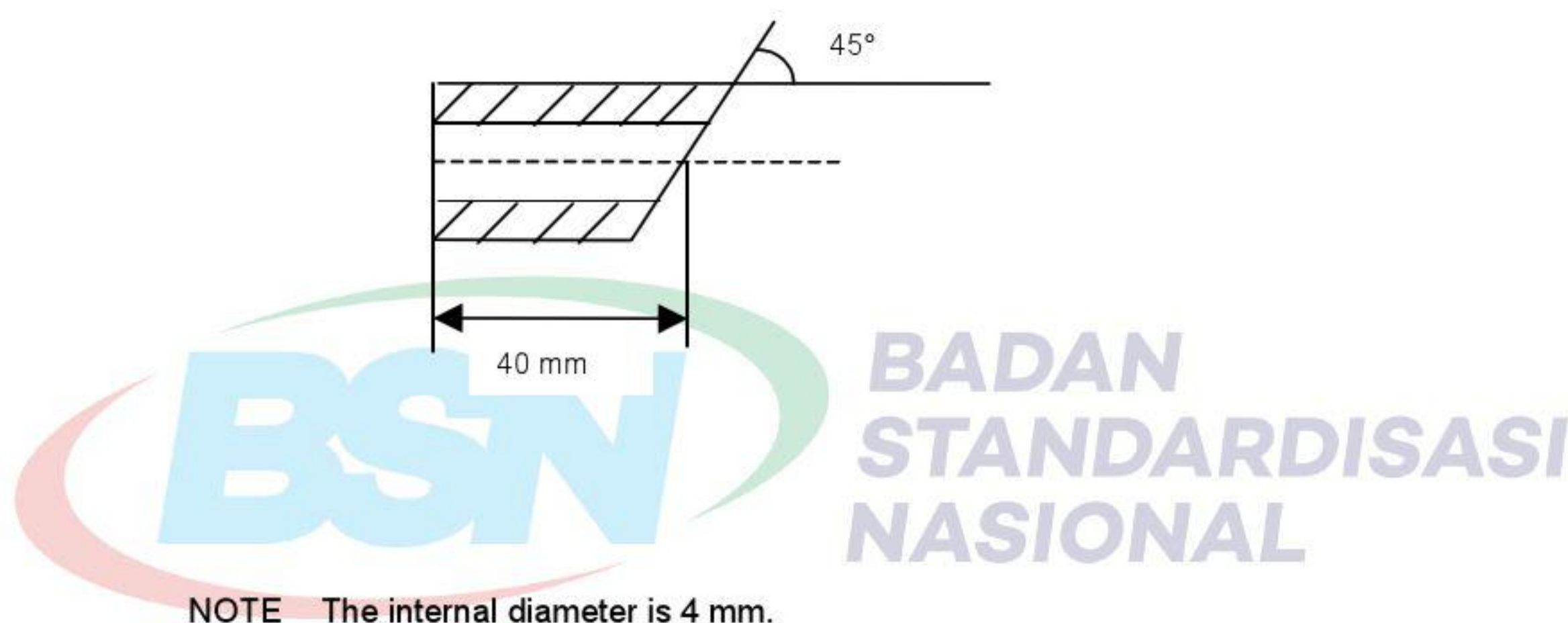



Figure 201.101 – Standard resistance

e) *Set the* SLEEP APNOEA BREATHING THERAPY EQUIPMENT *to the least favourable mode and flow pattern, as applicable, that generates a continuous pressure of 10 hPa (10 cmH_2O) at the* PATIENT-CONNECTION PORT.

NOTE The least favourable mode, breath type and flow pattern can vary by BREATHING GAS PATHWAY *configuration.*

f) *Using a microphone of the sound level meter complying with the requirements of type 1 instruments specified in IEC 61672-1:2013, measure the sound pressure levels at 10 positions in a hemisphere with a radius from the geometric centre of the* SLEEP APNOEA BREATHING THERAPY EQUIPMENT *as specified in 7.2 of ISO 3744:2010.*

g) *Calculate the A-weighted sound pressure level averaged over the measurement surface according to 8.1 of ISO 3744:2010.*

h) *Calculate the A-weighted sound power level according to 8.6 of ISO 3744:2010.*

i) *Verify that the A-weighted background level of extraneous noise is at least 6 dB below that measured during the test.*

j) *Take measurements using the frequency-weighting characteristic A and the time-weighting characteristic F on the sound level meter in a free field over a reflecting plane as specified in ISO 3744:2010. Average the values in accordance with subclause 8.1 of ISO 3744:2010.*

k) *Repeat b) to j) for each* HUMIDIFIER *provided with or specified in the* ACCOMPANYING DOCUMENTS.

l) *Ensure that the measured sound pressure level is less than that disclosed in the instructions for use.*

201.10 Protection against unwanted and excessive radiation HAZARDS

IEC 60601-1:2005+A1:2012, Clause 10 applies.

201.11 Protection against excessive temperatures and other HAZARDS

IEC 60601-1:2005+A1:2012, Clause 11 applies, except as follows:

201.11.1.2.2 APPLIED PARTS not intended to supply heat to a PATIENT

Amendment (add between the existing paragraphs):

Over the RATED flowrate range and at the maximum RATED operating temperature, the temperature of the delivered gas of SLEEP APNOEA BREATHING THERAPY EQUIPMENT, both with and without a humidifier, shall not exceed an energy equivalent to 43 °C and 100 % relative humidity (a specific enthalpy not to exceed 197 kJ/m^3 dry gas) when averaged over 120 s.

Table 201.101 contains examples of combinations of temperature and relative humidity with such a specific enthalpy.

Table 201.101 — Examples of permissible combinations of temperature and relative humidity

Temperature °C	Relative humidity %
43	100
44	95
45	90
48	76
50	68

201.11.6.4 Leakage

Amendment (add after existing text):

The MANUFACTURER of SLEEP APNOEA BREATHING THERAPY EQUIPMENT shall address in the RISK MANAGEMENT PROCESS the RISKS associated with the leaching or leaking of substances into the gas pathway. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction.

The gas pathways of a SLEEP APNOEA BREATHING THERAPY EQUIPMENT that contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction shall be marked as containing phthalates on the device itself or on the packaging. The symbols of EN 15986:2011 may be used. If the intended use of the SLEEP APNOEA BREATHING THERAPY EQUIPMENT includes treatment of children or treatment of pregnant or nursing women, a specific justification for the use of these phthalates shall be included in the RISK MANAGEMENT FILE. The instructions for use shall contain information on RESIDUAL RISKS for these PATIENT groups and, if applicable, on appropriate precautionary measures.

The SLEEP APNOEA BREATHING THERAPY EQUIPMENT should be designed to minimize health RISK due to reasonably foreseeable substances getting into the BREATHING GAS PATHWAY from the GAS OUTPUT PORT during NORMAL USE.

Check compliance by inspection of the RISK MANAGEMENT FILE for identification of the presence of substances which are carcinogenic, mutagenic or toxic to reproduction and justification for their use.

201.11.8 Additional requirements for interruption of the power supply/SUPPLY MAINS to ME EQUIPMENT

Amendment (add after existing text):

SLEEP APNOEA BREATHING THERAPY EQUIPMENT shall incorporate a means to allow spontaneous breathing by the PATIENT when the electrical or pneumatic power supply fails or falls outside the range for normal operation. This means may be provided by a MASK or ACCESSORY.

EXAMPLES A nasal MASK or an anti-asphyxiation valve in a full face MASK that complies with ISO 17510.

If this means is provided by the MASK or other ACCESSORY, the instructions for use shall include a warning to the effect that "Warning: Failure to use a MASK or ACCESSORY that permits spontaneous breathing can cause asphyxiation."

201.12 Accuracy of controls and instruments and protection against hazardous outputs

IEC 60601-1:2005+A1:2012, Clause 12 applies, except as follows:

201.12.1 * Accuracy of controls and instruments

Amendment (add after existing sentence):

The controls of SLEEP APNOEA BREATHING THERAPY EQUIPMENT shall be CLEARLY LEGIBLE under the conditions specified in the 201.7.1.2 of this standard.

Check compliance by application of the tests of 201.7.1.2.

Additional subclauses:

201.12.1.101 Stability of static AIRWAY PRESSURE ACCURACY (long-term accuracy)

The stability of the static AIRWAY PRESSURE ACCURACY for any type of SLEEP APNOEA BREATHING THERAPY EQUIPMENT when operating in NORMAL CONDITION shall be disclosed in the instructions for use, as the maximum bias error and maximum linearity error.

EXAMPLE ± (3,0 hPa + 5 % of the set pressure)

NOTE 1 This information should be expressed in graphical or tabular form.

The accuracy of the performance of the SLEEP APNOEA BREATHING THERAPY EQUIPMENT shall either be:

— determined for each BREATHING GAS PATHWAY configuration indicated in the instructions for use; or

— determined for the worst case BREATHING GAS PATHWAY configuration indicated in the instructions for use.

If worst case BREATHING GAS PATHWAY configurations are used, the rationale for their selection shall be documented in the RISK MANAGEMENT FILE.

Check compliance by inspection of the RISK MANAGEMENT FILE for the rationale, if applicable, and by inspection of the instructions for use with the following tests:

a) *Set up the SLEEP APNOEA BREATHING THERAPY EQUIPMENT for NORMAL USE according to Figure 201.102 with the pressure set to 10 hPa (10 cm H_2O) in CPAP mode. For BI-LEVEL PAP SLEEP APNOEA BREATHING THERAPY EQUIPMENT without a CPAP mode, adjust the inspiratory and expiratory pressures to the same value. Switch off all comfort features of the ME EQUIPMENT. Place the standard resistance (Figure 201.101) at the PATIENT-CONNECTION PORT.*

NOTE 2 Comfort features do include, but are not limited to, e.g. automatic start / stop function, fall-to-sleep ramps, automatic inspiratory pressure increase or automatic expiratory pressure decrease.

b) *Using a pressure-measuring device, measure the pressure at least once per second at the* PATIENT-CONNECTION PORT *of the* BREATHING GAS PATHWAY *and record, each minute, the average pressure over each averaging interval of 1 min for a period of 8 h.*

c) *Calculate the most positive and most negative pressure difference (if applicable) referenced to the set pressure on the* SLEEP APNOEA BREATHING THERAPY EQUIPMENT.

d) *Verify that the average measured static pressure is within the static* AIRWAY PRESSURE ACCURACY *limit disclosed in the instructions for use.*

Key
1 – SLEEP APNOEA BREATHING THERAPY EQUIPMENT
2 – BREATHING GAS PATHWAY
3 – standard resistance (see Figure 201.101)
4 – pressure meter
5 – PATIENT-CONNECTION PORT

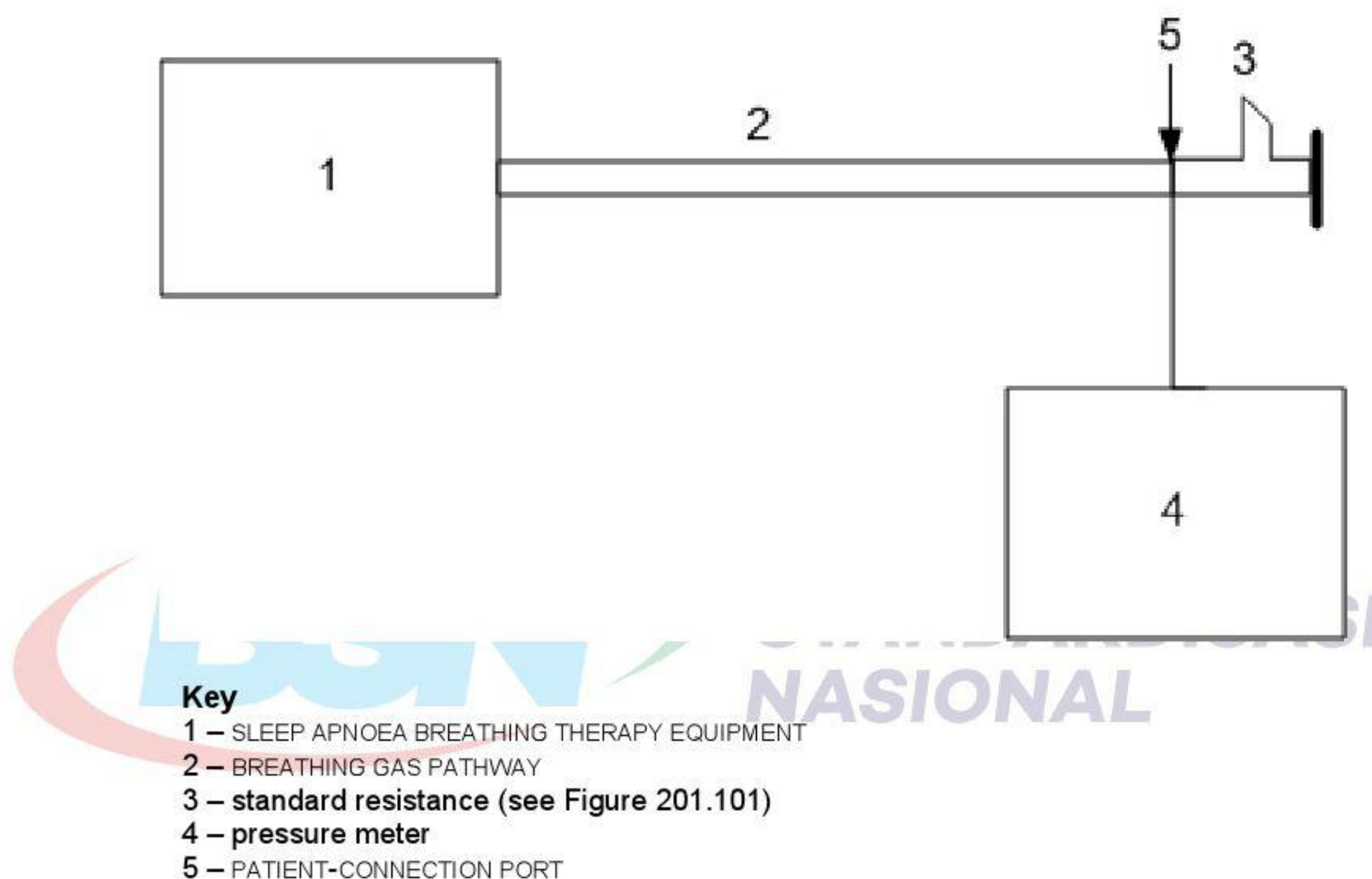



Figure 201.102 – Test set-up for static AIRWAY PRESSURE ACCURACY in NORMAL USE

201.12.1.102 Stability of dynamic AIRWAY PRESSURE ACCURACY (short-term accuracy)

201.12.1.102.1 CPAP mode

With the SLEEP APNOEA BREATHING THERAPY EQUIPMENT operating in CPAP mode in NORMAL CONDITION, the stability of the dynamic AIRWAY PRESSURE ACCURACY shall be disclosed in the instructions for use, as the maximum bias error and maximum linearity error.

EXAMPLE ± (3,0 hPa + 5 % of the set pressure)

NOTE 1 This information should be expressed in graphical or tabular form.

The accuracy of the performance of the SLEEP APNOEA BREATHING THERAPY EQUIPMENT shall either be:

— determined for each BREATHING GAS PATHWAY configuration indicated in the instructions for use; or

— determined for the worst case BREATHING GAS PATHWAY configuration indicated in the instructions for use.

If worst case BREATHING GAS PATHWAY configurations are used, the rationale for their selection shall be documented in the RISK MANAGEMENT FILE.

Check compliance by inspection of the RISK MANAGEMENT FILE *for the rationale, if applicable, and by inspection of the instructions for use with the following tests:*

a) *Connect the* PATIENT-CONNECTION PORT *to a pressure-measuring device and a pump that produces a sinusoidal cycle with an inspiratory:expiratory phase time (I/E ratio) of 1/1 and a breathing frequency of 10 breaths/min according to Figure 201.103. Switch off all comfort features of the* ME EQUIPMENT. *Monitor and measure the flowrate and pressure using a pressure- and flowrate-measuring device at the* PATIENT-CONNECTION PORT.

   NOTE 2 The deadspace of the test lung should be less than the tidal volume used.

   NOTE 3. All measurement uncertainties of the test apparatus used for these tests (specified in a) and b)) are to be included in the calculation of the results, i.e. uncertainties are to be added to the differences measured.

b) *Set the pressure to the minimum pressure setting.*

c) *Set lung parameters according to Table 201.102 with a tidal volume,* V_t, *of approximately 500 ml.*

d) *Simulate an apnoea event by turning the pump off for at least 1 min.*

e) *For each cycle, calculate the most positive and negative pressure difference from the set value. Average these results over a period of 5 min.*

f) *Record the pressure and flowrate waveforms. If necessary, adjust the settings until the breathing frequency and stroke volume match the desired settings.*

g) *Record the dynamic high and low pressure measurements as peak-to-peak values. Subtract the recorded dynamic low pressure from the recorded dynamic high pressure.*

h) *Verify that the average measured dynamic pressure is within the static* AIRWAY PRESSURE ACCURACY *limit disclosed in the instructions for use.*

i) *Repeat steps d) to h) for each set pressure indicated in Table 201.102.*

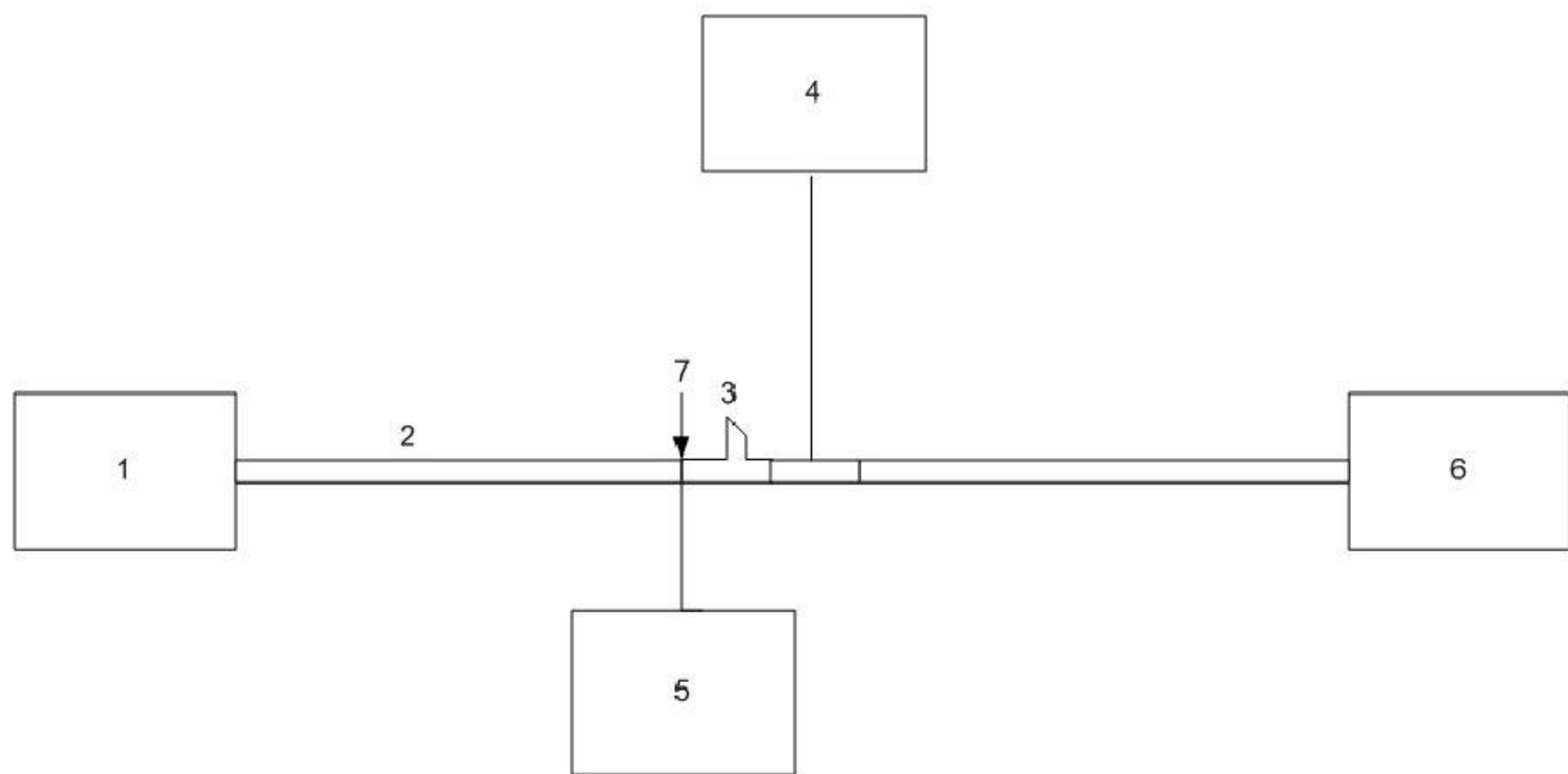
j) *Repeat b) to i) for each breath rate indicated in Table 201.102.*

Key
1 – SLEEP APNOEA BREATHING THERAPY EQUIPMENT
2 – BREATHING GAS PATHWAY
3 – Standard resistance (see Figure 201.101)
4 – Flow meter
5 – Pressure-measuring device
6 – Pump that produces a sinusoidal cycle
7 – PATIENT-CONNECTION PORT

Figure 201.103 – Test set-up for dynamic AIRWAY PRESSURE ACCURACY in NORMAL USE

Table 201.102 — Parameters for dynamic AIRWAY PRESSURE ACCURACY testing

	Fraction of the maximum adjustable pressure				
P [a] (hPa) (cm H_2O)	P_{min}	P_{min} + ¼ (P_{max} - P_{min})	P_{min} + ½ (P_{max} - P_{min})	P_{min} + ¾ (P_{max} - P_{min})	P_{max}
f (breaths/min)	10, 15, and 20				
V_t (ml)	500				

[a] Set pressure rounded to the nearest whole integer

Where

P_{min} is the minimum pressure setting.

P_{max} is the maximum pressure setting.

201.12.1.102.2 BI-LEVEL POSITIVE AIRWAY PRESSURE mode

With the SLEEP APNOEA BREATHING THERAPY EQUIPMENT operating in NORMAL CONDITION, the stability of the dynamic AIRWAY PRESSURE ACCURACY for both the inspiratory and expiratory pressure levels shall be disclosed in the instructions for use, as the mean and standard deviation of the error between the set values and the delivered values. The technical description shall disclose which percentage of

each inspiratory and expiratory phase is taken into the calculation for determining the accuracy as well as where these time slots are located within the inspiratory and the expiratory phases.

NOTE 1 This information should be expressed in graphical or tabular form.

The accuracy of the performance of the SLEEP APNOEA BREATHING THERAPY EQUIPMENT shall either be:

— determined for each BREATHING GAS PATHWAY configuration indicated in the instructions for use; or

— determined for the worst case BREATHING GAS PATHWAY configuration indicated in the instructions for use.

If worst case BREATHING GAS PATHWAY configurations are used, the rationale for their selection shall be documented in the RISK MANAGEMENT FILE.

Check compliance by inspection of the RISK MANAGEMENT FILE for the rationale, if applicable, and by inspection of the instructions for use with the following tests:

a) *Connect the PATIENT-CONNECTION PORT to a pressure-measuring device and a pump that produces a sinusoidal cycle with an inspiratory:expiratory phase time (I/E ratio) of 1/1 and a breathing frequency of 10 breaths/min according to Figure 201.103. Switch off all comfort features of the ME EQUIPMENT. Monitor and measure the flowrate and pressure using a pressure- and flowrate-measuring device at the PATIENT-CONNECTION PORT.*

   NOTE 2 The deadspace of the test lung should be less than the tidal volume used.

   NOTE 3 All measurement uncertainties of the test apparatus used for these tests (specified in a) and b)) are to be included in the calculation of the results, i.e. uncertainties are to be added to the differences measured.

b) *Set the pressure to the minimum pressure setting.*

c) *Set lung parameters according to Table 201.103 with a tidal volume, V_t, of approximately 500 ml.*

NOTE 4 To accommodate the different control mechanisms of different designs during the change from the inspiratory phase to the expiratory phase and vice versa measure the inspiratory pressure and expiratory pressures as specified in the technical description.

d) *Record the pressure and flowrate waveforms. If necessary, adjust the settings until the breathing frequency and stroke volume match the desired settings.*

e) *Simulate an apnoea event by turning the pump off for at least 1 min.*

f) *For each cycle, determine the extreme inspiratory pressure difference from the inspiratory set value. Calculate the mean and standard deviation of these pressures over a period of 5 min.*

g) *For each cycle, determine the extreme expiratory pressure difference from the expiratory set value. Calculate the mean and standard deviation of these pressures over a period of 5 min.*

h) *Verify that the mean and standard deviation of the dynamic inspiratory and expiratory pressure errors are within the limits disclosed in the instructions for use.*

i) *Repeat steps e) to h) for each set pressure indicated in Table 201.103.*

j) *Repeat b) to i) for each breath rate indicated in Table 201.103.*

Table 201.103 — Parameters for dynamic AIRWAY PRESSURE ACCURACY testing for POSITIVE AIRWAY PRESSURE mode

	Fraction of the maximum adjustable pressure				
P [a], inspiratory (hPa) (cm H_2O)	P_{min}+ 4	P_{min} + 2 + ¼ (P_{max} - P_{min})	P_{min} + 2 + ½ (P_{max} - P_{min})	P_{min} + 2 + ¾ (P_{max} - P_{min})	P_{max}
P [a], expiratory (hPa) (cm H_2O)	P_{min}	P_{min} - 2 + ¼ (P_{max} - P_{min})	P_{min} - 2 + ½ (P_{max} - P_{min})	P_{min} - 2 + ¾ (P_{max} - P_{min})	P_{max}- 4
f (breaths/min)	10, 15, and 20				
V_t (ml)	500				

[a] Set pressure rounded to the nearest whole integer

Where

P_{min} is the minimum pressure setting.

P_{max} is the maximum pressure setting.

201.12.1.103 Maximum flowrate

The flowrate capability of SLEEP APNOEA BREATHING THERAPY EQUIPMENT over the set pressure range shall be disclosed in the instructions for use. The disclosure may be in tabular form.

Check compliance by inspection of the instructions for use and with the following tests:

a) *Set up SLEEP APNOEA BREATHING THERAPY EQUIPMENT with a 1,9 ± 0,15 m BREATHING TUBE. Switch off all comfort features of the ME EQUIPMENT.*

b) *Apply a pressure-measuring device and flowrate meter to the PATIENT-CONNECTION PORT.*

c) *Apply an adjustable valve at the PATIENT-CONNECTION PORT.*

d) *Set the pressure to the minimum setting and adjust the valve to achieve (40 ± 2) l/min and measure the actual pressure delivered to the PATIENT-CONNECTION PORT.*

e) *Adjust the valve until the actual measured pressure is reduced by 1 hPa ± 0,1 hPa (1 cm H_2O ± 0,1 cm H_2O). Read the corresponding measured pressure and flowrate value.*

f) *Repeat step e) 10 times and record the average value of these 10 measurements.*

g) *Verify that the SLEEP APNOEA BREATHING THERAPY EQUIPMENT can deliver at least as much flow as is indicated in the instructions for use.*

h) *Repeat step d) to g) with each pressure as indicated in Table 201.104.*

Table 201.104 – SLEEP APNOEA BREATHING THERAPY EQUIPMENT flowrate performance at set pressures

	Test pressures [a]				
	P_{min}	P_{min} + ¼ (P_{max} - P_{min})	P_{min} + ½ (P_{max} - P_{min})	P_{min} + ¾ (P_{max} - P_{min})	P_{max}
Measured pressure at the PATIENT-CONNECTION PORT (hPa)					
Average flow at the PATIENT-CONNECTION PORT (l/min)					

[a] Set pressure rounded to the nearest whole integer

Where

P_{min} is the minimum pressure setting.

P_{max} is the maximum pressure setting.

201.12.4 Protection against hazardous output

Additional subclauses:

201.12.4.101 Measurement of AIRWAY PRESSURE

If SLEEP APNOEA BREATHING THERAPY EQUIPMENT is equipped with MONITORING EQUIPMENT to indicate the AIRWAY PRESSURE, the accuracy under steady-state conditions shall not be worse than ± (2 % of the full scale reading + 4 % of the actual reading). The full-scale reading shall not exceed the maximum value that can be achieved under SINGLE FAULT CONDITION. The site of actual measurement may be anywhere in the BREATHING GAS PATHWAY, but the indicated value shall be referenced to the PATIENT-CONNECTION PORT.

Check compliance by functional testing and inspection of the instructions for use.

201.12.4.102 * MAXIMUM LIMITED PRESSURE PROTECTION DEVICE

A PROTECTION DEVICE to prevent the AIRWAY PRESSURE from exceeding the MAXIMUM LIMITED PRESSURE of 30 hPa (30 cm H_2O) in NORMAL CONDITION and of 40 hPa (40 cm H_2O) in SINGLE FAULT CONDITION shall be provided.

Check compliance by functional testing in NORMAL CONDITION and SINGLE FAULT CONDITION.

201.12.4.103 * CO_2 rebreathing

SLEEP APNOEA BREATHING THERAPY EQUIPMENT shall be designed so that rebreathing of carbon dioxide is minimised to an acceptable level. Use of SLEEP APNOEA BREATHING THERAPY EQUIPMENT with a designated MASK or ACCESSORY that complies with ISO 17510:— may be used to comply with this requirement. In such a case, the ACCOMPANYING DOCUMENTS shall include the list of designated MASKS or ACCESSORIES or alternatively the necessary information to locate such a list.

EXAMPLE The address of the list on a website.

NOTE The design of the SLEEP APNOEA BREATHING THERAPY EQUIPMENT can be such that this requirement is satisfied without a designated MASK or ACCESSORY.

If this means is provided by the MASK or other ACCESSORY, the instructions for use shall include a warning to the effect that "Warning: Failure to use a mask or accessory that minimizes rebreathing of carbon dioxide or permits spontaneous breathing can cause asphyxiation."

Check compliance by application of the tests of Annex F of ISO 17510:—. If the SLEEP APNOEA BREATHING THERAPY EQUIPMENT provides the means of compliance, it shall be used as the flow source for the test.

201.13 HAZARDOUS SITUATIONS and fault conditions

IEC 60601-1:2005+A1:2012, Clause 13 applies.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

IEC 60601-1:2005+A1:2012, Clause 14 applies.

201.15 Construction of ME EQUIPMENT

IEC 60601-1:2005+A1:2012, Clause 15 applies, except as follows:

Additional subclause:

201.15.101 Mode of operation

SLEEP APNOEA BREATHING THERAPY EQUIPMENT shall be suitable for CONTINUOUS OPERATION.

Check compliance by inspection.

201.16 ME SYSTEMS

IEC 60601-1:2005+A1:2012, Clause 16 applies.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005+A1:2012, Clause 17 applies, except as follows:

Additional subclause:

201.17.101 Additional requirements for electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

NOTE SLEEP APNOEA BREATHING THERAPY EQUIPMENT is not considered a LIFE-SUPPORTING ME EQUIPMENT OR ME SYSTEM as defined in IEC 60601-1-2.

New clauses:

201.101 BREATHING GAS PATHWAY connectors

201.101.1 General

A conical BREATHING GAS PATHWAY connector shall be either a 15 mm or a 22 mm connector complying with ISO 5356-1:2004 or not engage with those connectors.

A non-conical connector shall not engage with a conical connector complying with ISO 5356-1:2004 unless they comply with the engagement, disengagement and leakage requirements of that standard.

The SMALL-BORE connectors of the BREATHING GAS PATHWAY, its parts or ACCESSORIES shall comply with ISO 80369-1:2010.

Check compliance by application of the tests of ISO 5356-1:2004, ISO 80369-1:2010 and functional testing.

201.101.2 Other named ports

201.101.2.1 PATIENT-CONNECTION PORT

The PATIENT-CONNECTION PORT shall be one of the following:

a) a female 15 mm conical connector complying with ISO 5356-1:2004;

b) a female 22 mm conical connector complying with ISO 5356-1:2004.

Check compliance by application of the tests of ISO 5356-1:2004.

201.101.2.2 GAS OUTPUT PORT

If provided, the GAS OUTPUT PORT shall be one of the following or not engage with any of the connectors of ISO 5356-1:2004.

a) a male 22 mm conical connector complying with ISO 5356-1:2004.

b) a male 15 mm conical connector complying with ISO 5356-1:2004.

Check compliance by application of the tests of ISO 5356-1:2004.

201.101.2.3 FLOW-DIRECTION-SENSITIVE COMPONENTS

Any OPERATOR-detachable FLOW-DIRECTION-SENSITIVE COMPONENT of the BREATHING GAS PATHWAY shall be so designed that it cannot be fitted in such a way that it presents an unacceptable RISK to the PATIENT.

Check compliance by inspection of OPERATOR-detachable FLOW-DIRECTION-SENSITIVE COMPONENTS and inspection of the RISK MANAGEMENT FILE.

201.101.2.4 Ancillary port

If an ancillary port is provided, it shall comply with ISO 80369-1:2010 and shall be provided with a means to secure closure after removal of an ACCESSORY connected to the ancillary port.

NOTE 1 It is expected that the RESP-125 (R1) connector of ISO 80369-2 will meet this criterion. The pressure range for this connector is specified for up to 125 hPa.

NOTE 2 An ancillary port is generally used for sampling of gases or for introduction of therapeutic aerosols.

Check compliance by inspection and application of the tests of ISO 80369-1:2010.

201.101.2.5 Monitoring probe port

If a port is provided for introducing a monitoring probe, it shall not be compatible with connectors specified in ISO 5356-1:2004, and shall be provided with a means to secure the probe in position and a means to secure closure after removal of the probe.

Check compliance by inspection and application of the tests of ISO 5356-1:2004.

201.102 Requirements for the BREATHING GAS PATHWAY and ACCESSORIES

201.102.1 * General

All BREATHING GAS PATHWAYS, their parts and ACCESSORIES shall comply with the requirements of this particular standard, whether they are produced by the MANUFACTURER of the SLEEP APNOEA BREATHING THERAPY EQUIPMENT or by another entity ("third-party manufacturer" or healthcare provider).

Check compliance by the tests of this standard.

201.102.2 Labelling

The MODEL OR TYPE REFERENCE of at least one compatible SLEEP APNOEA BREATHING THERAPY EQUIPMENT shall be disclosed in the ACCOMPANYING DOCUMENT provided with each BREATHING GAS PATHWAY and ACCESSORY, compliant with 201.102.1.

Statements shall be included in the ACCOMPANYING DOCUMENT of each BREATHING GAS PATHWAY, part and ACCESSORY to the effect that:

a) breathing gas pathways, their parts and accessories are validated for use with specific sleep apnoea breathing therapy equipment;

b) incompatible parts or accessories can result in degraded performance; and

c) the responsible organization is accountable for ensuring the compatibility of the sleep apnoea breathing therapy equipment and all of the parts or accessories used to connect to the patient before use.

Check compliance by inspection of the ACCOMPANYING DOCUMENT.

201.102.3 Humidification

Any HUMIDIFIER, including heated BREATHING TUBES, either incorporated into the SLEEP APNOEA BREATHING THERAPY EQUIPMENT or recommended for use with the SLEEP APNOEA BREATHING THERAPY EQUIPMENT or its BREATHING GAS PATHWAY, shall comply with ISO 8185:2007 (to be ISO 80601-2-74).

Check compliance by application of the tests of ISO 8185:2007.

201.102.4 BREATHING SYSTEM FILTER (BSF)

Any BSF, either incorporated into the SLEEP APNOEA BREATHING THERAPY EQUIPMENT or recommended for use with the SLEEP APNOEA BREATHING THERAPY EQUIPMENT or its BREATHING GAS PATHWAY, shall comply with the relevant requirements of ISO 23328-1:2003 and ISO 23328-2:2002.

Check compliance by application of the tests of ISO 23328-1:2003 and ISO 23328-2:2002.

201.103 FUNCTIONAL CONNECTION

201.103.1 General

BASIC SAFETY shall be maintained if connections to the FUNCTIONAL CONNECTION of a SLEEP APNOEA BREATHING THERAPY EQUIPMENT are disrupted or if the equipment connected to those parts fails.

Check compliance by functional testing.

201.103.2 * FUNCTIONAL CONNECTION to support remote supervision

SLEEP APNOEA BREATHING THERAPY EQUIPMENT should be equipped with a FUNCTIONAL CONNECTION that permits data transmission to and from the SLEEP APNOEA BREATHING THERAPY EQUIPMENT to support remote supervision of the equipment. The data transmission should be capable of transmitting the information described in Annex BB.

Check compliance by inspection.

201.104 Training

In the application of the requirements of IEC 62366:2007, Clause 7, training for the LAY OPERATOR shall be considered required.

NOTE Requirements for training are found in IEC 62366:2007, Clause 7.

Check compliance by inspection of the ACCOMPANYING DOCUMENT.

202 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests

IEC 60601-1-2:2014 applies, except as follows:

202.4.3.1 Configurations

Amendment (replace the second dash of 4.3.1 with):

— the SLEEP APNOEA BREATHING THERAPY EQUIPMENT operated using the conditions and test configuration of 201.12.1.101 a) and 201.12.1.101 b), respectively.

202.5.2.2.1 Requirements applicable to all ME EQUIPMENT and ME SYSTEMS

Amendment (add note to list element b)):

NOTE The requirements of this particular standard are not considered deviations or allowances.

Addition:

202.8.1.101 Additional general requirements

SLEEP APNOEA BREATHING THERAPY EQUIPMENT shall be tested according to the requirements for the HOME HEALTHCARE ENVIRONMENT.

The following degradations, if associated with BASIC SAFETY, shall not be allowed:

— component failures,

— changes in programmable parameters or settings,

— reset to default settings,

— change of operating mode, and

EXAMPLE Change from a BI-LEVEL POSITIVE AIRWAY PRESSURE to CPAP mode.

— static or dynamic pressure deviation of more than twice the AIRWAY PRESSURE ACCURACY limit disclosed in the instructions for use.

The SLEEP APNOEA BREATHING THERAPY EQUIPMENT may exhibit temporary degradation of performance (e.g. deviation from the performance indicated in the instructions for use) that does not affect BASIC SAFETY.

206 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability

IEC 60601-1-6:2010+A1:2013 applies except as follows:

For SLEEP APNOEA BREATHING THERAPY EQUIPMENT, the following shall be considered PRIMARY OPERATING FUNCTIONS:

a) if applicable, setting the LAY-OPERATOR-adjustable controls;

b) assembling the BREATHING GAS PATHWAY, including connection of the detachable parts of the BREATHING GAS PATHWAY, to the SLEEP APNOEA BREATHING THERAPY EQUIPMENT;

EXAMPLES HUMIDIFIER, nebulizer, water-trap, tubing, BSF

c) starting the SLEEP APNOEA BREATHING THERAPY EQUIPMENT from power-off or standby; and

d) turning off or switching to standby the SLEEP APNOEA BREATHING THERAPY EQUIPMENT.

The following OPERATOR interactions associated with therapy also shall be considered PRIMARY OPERATING FUNCTIONS:

NOTE For the purposes of this standard the following functions are considered PRIMARY OPERATING FUNCTIONS even though they are not performed on the SLEEP APNOEA BREATHING THERAPY EQUIPMENT'S OPERATOR-EQUIPMENT INTERFACE.

e) setting up the HUMIDIFIER to condition gases delivered through the BREATHING GAS PATHWAY into the PATIENT; and

f) adding oxygen to the gas flowing into the PATIENT.

208 Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

IEC 60601-1-8:2006+A1:2012 applies.

211 Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

IEC 60601-1-11:— applies except as follows:

Subclause 8.4 does not apply.

Annexes of the general standard apply, except as follows.

Annex C
(informative)

Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS

201.C.1 Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts

Additional requirements for marking on the outside of a SLEEP APNOEA BREATHING THERAPY EQUIPMENT, its parts and ACCESSORIES are found in Table 201.C.101.

Table 201.C.101 — Marking on the outside of a SLEEP APNOEA BREATHING THERAPY EQUIPMENT, its parts or ACCESSORIES

Description of marking	Subclause
Any particular storage and/or handling instructions	201.7.2.101 a)
Any particular warnings and/or precautions relevant to the immediate operation of the SLEEP APNOEA BREATHING THERAPY EQUIPMENT	201.7.2.101 b)
Containing phthalates, if applicable	201.11.6.4
For ACCESSORIES, an indication of any limitations or adverse effects on the BASIC SAFETY of the SLEEP APNOEA BREATHING THERAPY EQUIPMENT, if applicable	201.7.2.4.101
For ACCESSORIES or BREATHING GAS PATHWAYS, containing natural rubber latex, if applicable	201.7.2.13.101
For packages, description of the contents	201.7.2.17.101
For packages, identification reference to the batch, type or serial number	201.7.2.17.101
For packages containing natural rubber latex, if applicable	201.7.2.17.101
Name or trade name and address of the MANUFACTURER to which the RESPONSIBLE ORGANIZATION can refer	201.7.9.1
Where appropriate, OPERATOR-accessible parts or ACCESSORIES, an arrow indicating the direction of the flow for FLOW-DIRECTION-SENSITIVE COMPONENTS that are OPERATOR-removable without the use of a TOOL	201.7.2.101 c)
Where appropriate, OPERATOR-accessible SLEEP APNOEA BREATHING THERAPY EQUIPMENT, parts or accessories, a warning not to obstruct the gas intake port	201.7.2.101 d)
Where appropriate, OPERATOR-accessible SLEEP APNOEA BREATHING THERAPY EQUIPMENT, parts or ACCESSORIES, use of an appropriate BREATHING SYSTEM FILTER is required	201.7.2.101 e)
Where appropriate, OPERATOR-accessible SLEEP APNOEA BREATHING THERAPY EQUIPMENT, parts or ACCESSORIES, methods of cleaning the BREATHING SYSTEM FILTER	201.7.2.101 f)
Where the MANUFACTURER does not have an address within the locale, an authorized representative within the locale to which the RESPONSIBLE ORGANIZATION can refer	201.7.9.1

201.C.2 ACCOMPANYING DOCUMENTS, general

Additional requirements for general information to be included in the ACCOMPANYING DOCUMENTS of a SLEEP APNOEA BREATHING THERAPY EQUIPMENT or its parts are found in Table 201.C.102.

Table 201.C.102 — ACCOMPANYING DOCUMENTS, general

Description of requirement	Subclause
Declared tolerances including the measurement uncertainty of the measurement used to determine the specification	201.5.101.2
For each BREATHING GAS PATHWAY or ACCESSORY, the MODEL OR TYPE REFERENCE of at least one compatible SLEEP APNOEA BREATHING THERAPY EQUIPMENT	201.102.2
For each BREATHING GAS PATHWAY, part or ACCESSORY, a statement to the effect that breathing gas pathways, their parts and accessories are validated for use with specific sleep apnoea breathing therapy equipment	201.102.2 a)
For each BREATHING GAS PATHWAY, part or ACCESSORY, a statement to the effect that incompatible parts can result in degraded performance	201.102.2 b)
For each BREATHING GAS PATHWAY, part or ACCESSORY, a statement to the effect that the responsible organization is responsible for ensuring the compatibility of the sleep apnoea breathing therapy equipment and all of the parts used to connect to the patient before use	201.102.2 c)
List of designated MASKS or ACCESSORIES needed to minimise rebreathing of carbon dioxide, if required	201.12.4.103
Name or trade name and address of the MANUFACTURER to which the RESPONSIBLE ORGANIZATION can refer	201.7.9.1
Necessary information to locate a list of designated MASKS or ACCESSORIES needed to minimise rebreathing of carbon dioxide, if required	201.12.4.103
Training is necessary for the LAY OPERATOR	201.104
Where the MANUFACTURER does not have an address within the locale, an authorized representative within the locale to which the RESPONSIBLE ORGANIZATION can refer	201.7.9.1

201.C.3 ACCOMPANYING DOCUMENTS, instructions for use

Additional requirements for information to be included in the instructions for use of a SLEEP APNOEA BREATHING THERAPY EQUIPMENT or its parts are found in Table 201.C.103.

Table 201.C.103 — Instructions for use *(1 of 2)*

Description of requirement	Subclause
Any particular warnings and/or precautions relevant to the immediate operation of the sLEEP APNOEA BREATHING THERAPY EQUIPMENT	201.7.2.101 b)
Any restrictions on the positioning of components within the BREATHING GAS PATHWAY, if applicable	201.7.9.2.14.101 a)
Details of any restrictions on the sequence of components within the BREATHING GAS PATHWAY, if applicable	201.7.9.2.14.101 c)
Diagram of the SLEEP APNOEA BREATHING THERAPY EQUIPMENT, if applicable	201.7.9.2.14.101 b)
Dynamic AIRWAY PRESSURE ACCURACY as the maximum bias error and maximum linearity error for CPAP mode, if applicable	201.12.1.102.1
Dynamic AIRWAY PRESSURE ACCURACY as the maximum bias error and maximum linearity error for BIPAP, mode if applicable	201.12.1.102.2
Explanation of the meaning of the IP classification	201.7.9.2.9.101
For ACCESSORIES, an indication of any limitations or adverse effects on the BASIC SAFETY of the SLEEP APNOEA BREATHING THERAPY EQUIPMENT, if marking the ACCESSORY is not practicable, if applicable	201.7.2.4.101

Table 201.C.103 — *(2 of 2)*

Description of requirement	Subclause
For ACCESSORIES or BREATHING GAS PATHWAYS, containing natural rubber latex, if applicable	201.7.2.13.101
For SLEEP APNOEA BREATHING THERAPY EQUIPMENT, its parts or ACCESSORIES that contain phthalates information on residual risks for children or treatment of pregnant or nursing women and, if applicable, on appropriate precautionary measures	201.11.6.4
For the SLEEP APNOEA BREATHING THERAPY EQUIPMENT, dependent on a MASK or ACCESSORY to allow spontaneous breathing, a warning to the effect that failure to use a mask or accessory that permits spontaneous breathing can cause asphyxiation.	201.11.8
For the SLEEP APNOEA BREATHING THERAPY EQUIPMENT, its parts or ACCESSORIES intended for single use, information on known characteristics and technical factors known to the MANUFACTURER that could pose a RISK if reused	201.7.9.2.1.101 a)
If applicable, the procedure necessary to determine the state of the INTERNAL ELECTRICAL POWER SOURCE	201.7.9.2.9.101
Maximum flowrate of SLEEP APNOEA BREATHING THERAPY EQUIPMENT over the set pressure range in tabular form	201.12.1.103
Sound power level	201.9.6.2.1.101
Sound pressure level	201.9.6.2.1.101
Specification of the INTAKE PORT filter including, but not limited to, the minimum particle size of retention, the retention rate, physical dimension of the filter, the maximum duration of use and the details on how to replace this filter	201.7.9.2.14.101 d)
Specification of the BREATHING SYSTEM FILTER including, but not limited to, the specifications of the filter, including the volume, the compliance, the resistance over the flow range, the maximum duration of use and the details on how to replace this filter	201.7.9.2.14.101 e)
Stability of the static AIRWAY PRESSURE ACCURACY as the maximum bias error and maximum linearity error	201.12.1.101
Statement to the effect that the therapeutic pressure setting has to be determined for each patient individually with the configuration of the equipment to be used, including accessories	201.7.9.2.5.101 a)
Statement to the effect that the proper placement and positioning of the patient interface is critical to the consistent operation of this equipment	201.7.9.2.5.101 b)
Warning statement to the effect that "WARNING: Nebulisation or humidification can increase the resistance of breathing system filters and that the operator needs to monitor the breathing system filter frequently for increased resistance and blockage to ensure the delivery of the therapeutic pressure."	201.7.9.2.2.101 c)
Warning statement to the effect that "WARNING: The equipment shall not be covered or positioned in such a way that the operation or performance of the equipment is adversely affected, including applicable examples	201.7.9.2.2.101 a)
Warning to the effect that "WARNING: Appropriate masks and accessories need to be used with the equipment to ensure the delivery of the therapeutic pressure and to minimize CO_2 rebreathing, unless not applicable	201.7.9.2.2.101 e)
Warning to the effect that "WARNING: Sources of oxygen should be located more than 1 m from the equipment to avoid the risk of fire and burns.", unless the sleep apnoea breathing therapy equipment is intended for use with an oxygen concentration above ambient	201.7.9.2.2.101 b)

201.C.4 ACCOMPANYING DOCUMENTS, technical description

Additional requirements for information to be included in the technical description of a SLEEP APNOEA BREATHING THERAPY EQUIPMENT or its parts are found in Table 201.C.104.

Table 201.C.104 — Technical description

Description of requirement	Subclause
Description of the comfort features and their range of adjustment (e.g. automatic start / stop function, fall to sleep ramps, automatic inspiratory pressure increase or automatic expiratory pressure decrease), if provided	201.7.9.3.1.101 f)
For ME EQUIPMENT without a respiratory pressure measuring device, the stability of pressure control between recommended maintenance times, if applicable	201.7.9.3.1.101 d)
MAXIMUM LIMITED PRESSURE	201.7.9.3.1.101 b)
Means of transitioning between levels in BI-LEVEL POSITIVE AIRWAY PRESSURE mode	201.7.9.3.1.101 e)
Percentage of each inspiratory and expiratory phase that is used for the calculation determining the accuracy as well as where within the inspiratory and expiratory phases the percentage slot is taken	201.12.1.102.2
Pneumatic diagram of the SLEEP APNOEA BREATHING THERAPY EQUIPMENT	201.7.9.3.1.101 a)
RATED range of the set AIRWAY PRESSURE during NORMAL USE, if adjustable	201.7.9.3.1.101 b)
Statement to the effect that combinations with other medical devices can alter the performance of the equipment, if applicable	201.7.9.3.1.101 g)
Statement to the effect that the responsible organization should ensure the compatibility of the equipment and all of the parts and accessories used to connect to the patient before use	201.7.9.3.1.101 c)
Statement to the effect that the responsible organization should ensure that the therapeutic pressure setting were determined for the patient individually with the configuration of the equipment to be used, including accessories	201.7.9.3.1.101 c)
Statement to the effect that the responsible organization should periodically reassess the setting(s) of the therapy for effectiveness	201.7.9.3.1.101 c)

Annex D
(informative)

Symbols on marking

Annex D of the general standard applies, except as follows:

Addition:

Table 201.D.1.101 — Additional symbols on marking

No	Symbol	Reference	Title
1	LOT	ISO-7000-2492 Symbol 5.1.5 ISO 15223-1:2012	Batch code
2	REF	ISO-7000-2493 Symbol 5.1.6 ISO 15223-1:2012	Catalogue number
3	SN	ISO-7000-2498 Symbol 5.1.7 ISO 15223-1:2012	Serial number
4	LATEX	ISO-7000-2725 Symbol 5.4.5 ISO 15223-1:2012	Contains or presence of [natural rubber latex]

Additional Annexes:

Annex AA
(informative)

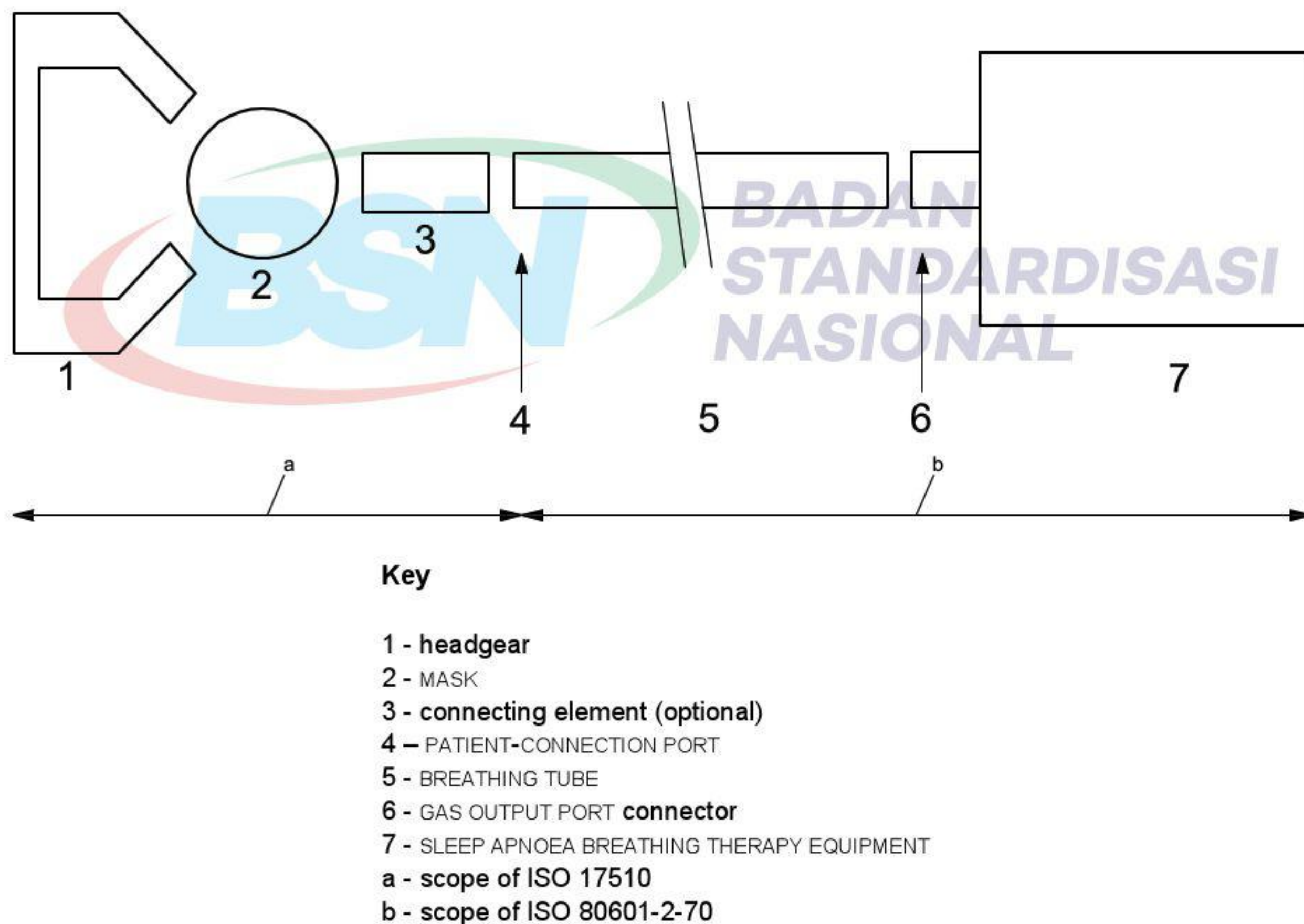
Particular guidance and rationale

AA.1 General guidance

This Annex provides rationale for some requirements of this document and is intended for those who are familiar with the subject of this document but who have not participated in its development. An understanding of the rationales underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of this document necessitated by those developments.

Figure AA.1 is a typical example of a series of component arrangements of ISO 80601-2-70 and ISO 17510. It is intended to enhance comprehension of the combination of SLEEP APNOEA BREATHING THERAPY EQUIPMENT and MASKS and application ACCESSORIES, as well as to clarify the scope of the related standards.

Key

1 - headgear
2 - MASK
3 - connecting element (optional)
4 – PATIENT-CONNECTION PORT
5 - BREATHING TUBE
6 - GAS OUTPUT PORT connector
7 - SLEEP APNOEA BREATHING THERAPY EQUIPMENT
a - scope of ISO 17510
b - scope of ISO 80601-2-70

NOTE 1 The EXHAUST PORT can be located in the connecting element (3), the MASK (2) or the SLEEP APNOEA BREATHING THERAPY EQUIPMENT (7).

NOTE 2 A HUMIDIFIER can be integral to the SLEEP APNOEA BREATHING THERAPY EQUIPMENT (7) or in series with the BREATHING TUBE (5).

NOTE 3 A BREATHING SYSTEM FILTER can be placed in series with the BREATHING TUBE (5).

Figure AA.1 – Relationship of the components of SLEEP APNOEA BREATHING THERAPY EQUIPMENT and MASKS and application ACCESSORIES and the related standards

AA.2 Rationale for particular clauses and subclauses

The numbering of the following rationales corresponds to the numbering of the clauses and subclauses in this document. The numbering is, therefore, not consecutive.

Subclause 201.1.1 – Scope

The field of application encompasses CPAP equipment, BI-LEVEL POSITIVE AIRWAY PRESSURE EQUIPMENT, and SELF-ADJUSTING positive AIRWAY PRESSURE EQUIPMENT intended for sleep apnoea breathing therapy. SLEEP APNOEA BREATHING THERAPY EQUIPMENT rely on both the design of the SLEEP APNOEA BREATHING THERAPY EQUIPMENT to minimize RISK of asphyxia and the defence mechanisms of the PATIENT to respond to SINGLE FAULT CONDITIONS and arouse the PATIENT from sleep, thereby allowing the PATIENT to remove himself from potential HARM. Therefore, this standard deals extensively with the performance standard for SLEEP APNOEA BREATHING THERAPY EQUIPMENT to ensure the delivery of the therapeutic pressure and prevent asphyxia.

SLEEP APNOEA BREATHING THERAPY EQUIPMENT can be used in healthcare facilities, at home, in ships, in aircraft or in other transport situations.

Subclause 201.4.3.101 – Additional requirements for ESSENTIAL PERFORMANCE

SLEEP APNOEA BREATHING EQUIPMENT has no ESSENTIAL PERFORMANCE. PATIENTS diagnosed with OSA are capable of spontaneously breathing and do not require additional ventilation support. In the absence of treatment (e.g. power failure or loss of therapy or other likely/foreseeable events) where performance is lost or degraded beyond the limits specified by the MANUFACTURER, the PATIENT does not suffer any adverse effects requiring immediate medical intervention. This means that a loss in performance of SLEEP APNOEA BREATHING EQUIPMENT does not result in an unacceptable RISK. This is why no ALARM CONDITIONS are required when therapy is lost or degraded.

Nonetheless, SLEEP APNOEA BREATHING EQUIPMENT is expected to provide effective therapy in NORMAL CONDITION even though loss of that therapy is not considered an unacceptable RISK. This is why pressure is evaluated in lieu of ESSENTIAL PERFORMANCE as an acceptance criterion (i.e., pressure does not change by more than twice the AIRWAY PRESSURE ACCURACY limit disclosed in the instructions for use). The test method specified in 202.6.2.1.10, together with the configuration specified in 201.12.1.101.a) provide a method for evaluating pressure with a sampling period of one second. The duration of test should be at least twice the dwell time for the intervention that is being evaluated.

Subclause 201.4.6 – ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT

Since the ACCESSORIES of SLEEP APNOEA BREATHING THERAPY EQUIPMENT are likely to be draped over or around the PATIENT, they are likely to come into direct contact with the PATIENT during NORMAL USE. Additionally, the gas pathways conduct fluids into or out of the PATIENT. As such, the gas pathways of the SLEEP APNOEA BREATHING THERAPY EQUIPMENT and its ACCESSORIES need to be investigated regarding biocompatibility and compatibility with substances that might pass into the PATIENT via the gas pathways. Also of concern are electrical HAZARDS should any circuitry be incorporated into the ACCESSORIES. By ensuring that the gas pathways are subject to the requirements for APPLIED PARTS, these issues are addressed by the requirements already in the general standard.

Subclause 201.5.101.2 – SLEEP APNOEA BREATHING THERAPY EQUIPMENT testing errors

When testing SLEEP APNOEA BREATHING THERAPY EQUIPMENT performance several of the test parameters cannot be measured without a significant degree of measurement uncertainty due to limitations of the accuracy that can be achieved, particularly when measuring volumes by the integration of rapidly changing flows.

Because of the relative significance of these uncertainties, it is important that MANUFACTURERS allow for them when declaring parameter accuracy.

Similarly, it is important for a third-party tester also to recognise the significance of the uncertainty in their own measurements when testing to this standard.

In practice, this means that, for example, if a MANUFACTURER determines that a parameter has a tolerance of ± 7 % but that the measurement uncertainty is ± 3 % then a parameter tolerance of ± 10 % is declared. If a third-party tester subsequently obtains an error of the measured value for that parameter of ± 15 %, with a measurement uncertainty of ± 5 %, then the third-party tester has to accept the MANUFACTURER'S claim.

Furthermore, the MANUFACTURER is required to disclose the measurement uncertainty for each declared value in order to provide both information to the RESPONSIBLE ORGANIZATION and guidance for a third-party tester as to the needed measurement accuracy when testing to this standard.

Subclause 201.7.1.2 – Legibility of markings

In order to change the settings of SLEEP APNOEA BREATHING THERAPY EQUIPMENT BREATHING THERAPY EQUIPMENT, the OPERATOR needs to be within an arm's length of the control.

Subclause 201.7.9.1 – Additional general requirements

Where the MANUFACTURER of a ME EQUIPMENT is not located in the same geographical locale as the OPERATOR or RESPONSIBLE ORGANIZATION of the ME EQUIPMENT, it is important that contact details are provided for a representative within the locale who is available for post-market surveillance reporting and who can respond to enquiries. Where this is not the MANUFACTURER, contact details for the MANUFACTURER also are provided. In many jurisdictions, this is a requirement of authorities having jurisdiction.

Subclause 201.7.9.3.1.101 – Additional general requirements

In this standard covering the treatment of obstructive sleep apnoea, control of the CPAP or BI-LEVEL POSITIVE AIRWAY PRESSURES in response to the PATIENT'S breathing is achieved by a classical control loop where the SLEEP APNOEA BREATHING THERAPY EQUIPMENT responds when the desired treatment pressure does not equal the measured pressure. This is achieved by an increase or decrease in motor speed until the equilibrium (treatment = measured pressure) has been re-established. In the case of SLEEP APNOEA BREATHING THERAPY EQUIPMENT providing BI-LEVEL POSITIVE AIRWAY PRESSURE there are two treatment pressures, inspiratory positive airway pressure (IPAP) and expiratory positive airway pressure (EPAP). The difference between these two values is referred to as the pressure support (PS) value expressed in hPa or cmH_2O. The PS value is set by the clinician and is typically 2 hPa (2 cmH_2O) to 3 hPa (3 cmH_2O). When the PATIENT breathes, the SLEEP APNOEA BREATHING THERAPY EQUIPMENT responds in the same manner as the CPAP control loop in synchronisation with the PATIENT'S breathing pattern.

Unlike ventilators indicated for lung ventilation (e.g. respiratory failure or life support), SLEEP APNOEA BREATHING THERAPY EQUIPMENT providing BI-LEVEL POSITIVE AIRWAY PRESSURE does not have a settable "trigger sensitive" function which is typically used to assist in the PROCESS of ventilator assist to the PATIENT or to provide a means to assist weaning to the PATIENT off the ventilator if desired by the clinician. This feature is settable by the clinician and is typically settable by a negative pressure value or a positive flow value over time (e.g. 20 ms - 100 ms).

Subclause 201.9.6.2.1.101 – Additional requirements for audible acoustic energy

Noise emissions are especially disturbing if the noise includes tonal components. Therefore it is recommended that the tonal components of noise be determined additionally. [14]

For undisturbed sleep, the World Health Organization recommends that the sound pressure level should not exceed 30 dB(A). MANUFACTURERS are encouraged to strive for lower sound pressure levels.

Subclause 201.12.1 – Accuracy of controls and instruments

The PATIENT does not need to read the controls of SLEEP APNOEA BREATHING THERAPY EQUIPMENT while sleeping. The intended use of the equipment is to improve sleep. Not lighting the controls is not a relevant HAZARD for the use of SLEEP APNOEA BREATHING THERAPY EQUIPMENT.

Subclause 201.12.4.102 – MAXIMUM LIMITED PRESSURE PROTECTION DEVICE

Nowadays a great number of SLEEP APNOEA BREATHING THERAPY EQUIPMENT includes CPAP as well as BI-LEVEL POSITIVE AIRWAY PRESSURE modes. Sometimes even modes with more than 2 pressure levels are utilized. Considering the fact that the RISKS related to the supply of high breathing system pressures for all PATIENTS is similar and independent of the mode in which the SLEEP APNOEA BREATHING THERAPY EQUIPMENT is used and considering the fact that all SLEEP APNOEA BREATHING THERAPY EQUIPMENT are used with open application systems (i.e. leaky MASKS), the committee considered that only one set of maximum pressure limitation for NORMAL and SINGLE FAULT CONDITION should be specified. The higher of the two previous limits was chosen.

Subclause 201.12.4.103 – CO_2 rebreathing

Sleep apnoea therapy BREATHING GAS PATHWAYS differ from most other BREATHING GAS PATHWAYS in the design of the inspiratory and expiratory breathing pathways in that they share a common conduit, namely the BREATHING TUBE connecting the sleep apnoea flow generator to the PATIENT-CONNECTION PORT. The BREATHING TUBE contains a mixture of fresh and expired gases. This design has important consequences for the potential for rebreathing of carbon dioxide and thereby the inspired oxygen concentration. Therefore the design and configuration of SLEEP APNOEA BREATHING THERAPY EQUIPMENT and its MASKS and ACCESSORIES have a major impact on the potential for rebreathing of carbon dioxide and thereby the inspired oxygen concentration.

Subclause 201.102.1 – General

It is the responsibility of the MANUFACTURER of SLEEP APNOEA BREATHING THERAPY EQUIPMENT ACCESSORIES to VERIFY that their product complies with the requirements of this particular standard.

Subclause 201.103.2 – FUNCTIONAL connection to support remote supervision

See Annex BB.

Annex BB
(informative)

Data interface requirements

BB.1 Background and purpose

Heightened interest in monitoring and controlling of SLEEP APNOEA BREATHING THERAPY EQUIPMENT, as well as accountability and responsiveness of the parties involved has become evident on an international scale. Consequently, PATIENTS, caregivers, clinicians, service providers, and payers have begun the systematic definition and collection of information with regard to monitoring the performance of SLEEP APNOEA BREATHING THERAPY EQUIPMENT. This trend is also concomitantly driven by an enhanced data infrastructure. In order to establish a common definition for monitoring the sleep apnoea therapy performance, explicit criteria need be applied to choosing and defining parameters. This framework is intended to inform about a common definition of sleep apnoea therapy parameters. The selection is based on some agreement about what is to be monitored, and for what purpose.

It is important to note that any data collection must be carried out according to privacy and confidentiality legislation and ethical principles.

A harmonized effort to develop internationally accepted sleep apnoea therapy indicators will not only foster increasingly robust cross-national analyses, but may also facilitate the development of comparable data that can be used as a basis for the setting of international benchmarks.

The standardization of data available from SLEEP APNOEA BREATHING THERAPY EQUIPMENT is intended to help to eliminate the current shortcomings and significantly contribute to the improvement of the therapy. This approach seeks to provide a definition that will be used across SLEEP APNOEA BREATHING THERAPY EQUIPMENT for providing therapy data independent of the MANUFACTURER or what mechanisms are used to transport the data, either locally or remotely, to a healthcare professional. This approach ensures comparability between data regardless of the transport mechanism chosen to be most appropriate for a PATIENT situation, it also provides for flexible and cost-effective integration into disparate systems that healthcare professionals can be using for PATIENT data management. This approach also maintains comparability between data while allowing advancement in data transport technology to provide solutions that better meet PATIENT, caregiver, clinician, service provider and payer needs. As such, the definition of specific communication interface hardware or software considerations such as protocols or transport mediums is outside of the scope of this standard.

A number of monitoring requirements exist for sleep apnoea therapy, depending upon the PATIENT, caregiver, clinician, service provider, and payer needs, which require various levels of data. This standard seeks to define the data that SLEEP APNOEA BREATHING THERAPY EQUIPMENT are required to provide to meet the objectives of these users.

The following categories of data are defined:

— **Parameters and units of measurement:** Parameters and units of measurement used within the SLEEP APNOEA BREATHING THERAPY EQUIPMENT

— **Equipment identification:** Information identifying the SLEEP APNOEA BREATHING THERAPY EQUIPMENT

— **Session compliance monitoring:** Data providing evidence of PATIENT compliance to therapy

— **Session efficacy monitoring:** Data providing parameters related to the effectiveness of the treatment

NOTE This is in addition to compliance monitoring.

— **Equipment therapy settings:** Therapy settings provided by SLEEP APNOEA BREATHING THERAPY EQUIPMENT

— **Service monitoring:** Indicators relating to preventative or corrective maintenance of the SLEEP APNOEA BREATHING THERAPY EQUIPMENT and its ACCESSORIES

All SLEEP APNOEA BREATHING THERAPY EQUIPMENT should provide the information to enable identification of the SLEEP APNOEA BREATHING THERAPY EQUIPMENT. Implementation of any further data levels is optional.

BB.2 Data definition

Table BB.101 defines the information, which identifies the pressure and flowrate units and the pressure and leakage percentiles, used in the data set.

Table BB.101 – Parameters and units of measurement

Parameter	Description	Type
Pressure units	Specification of the units of measurement for pressure related data	Units of measurement selected: (cmH_2O or hPa)
Flowrate units	Specification of the units of measurement for flowrate related data	Value selected: (l/min or l/s)
Pressure / Leakage percentile	Specification of the percentile used for flowrate and leakage percentile calculation	Value selected: (90 or 95)

Table BB.102 defines SLEEP APNOEA BREATHING THERAPY EQUIPMENT identification data.

Table BB.102 – Equipment identification

Parameter	Description	Type
Equipment MANUFACTURER	Identification of the MANUFACTURER of the equipment	Text string
Equipment model	Identification of the product or model number of the equipment	Text string
Equipment serial number	The identification number of the equipment	Text string
Equipment software version	Identification of the software version implemented in the equipment	Text string
NOTE More than one software version can need to be communicated from the equipment.		

Table BB.103 defines data required for compliance monitoring.

A set of data should be provided for a therapy session.

Table BB.103 – Session compliance monitoring

Parameter	Description	Type
Therapy stop date / time	The current UTC (Universal Time Coordinated) date and time when the usage session was stopped	ISO 8601 Date Time: (YYYY-MM-DDThh:mm:ssZ)
Hours of flow generation	Number of hours the equipment is powered on and providing flow for the usage session	Value: (h)
Hours of PATIENT use	Number of hours the equipment is providing therapy to the PATIENT for the usage session	Value: (h)

Table BB.104 defines data required for efficacy monitoring.

A set of measured and calculated values should be provided for each therapy session.

Table BB.104 – Session efficacy monitoring

Parameter	Description	Type
AHI (apnoea hypopnea index)	The average number of apnoea and hypopnea events occurring per hour of the therapy session.	Value: (events/h)
Percentile pressure	The 90th or 95th percentile AIRWAY PRESSURE	Value: (cmH_2O or hPa)
Percentile leakage	The 90th or 95th percentile leakage flowrate	Value: (l/min or l/s)
Average pressure	The average pressure for the therapy session	Value: (cmH_2O or hPa)
Average leakage	The average system leakage flowrate for the therapy session	Value: (l/min or l/s)
SLEEP APNOEA BREATHING THERAPY EQUIPMENT supporting detailed event recording		
Apnoea event	List of the date time of each apnoea event stop and the length of each apnoea event	List of: ISO 8601 Date Time (YYYY-MM-DDThh:mm:ssZ) Value: (s)
Hypopnea event	List of the date time of each hypopnea event stop and the length of each hypopnea event	List Of: ISO 8601 Date Time (YYYY-MM-DDThh:mm:ssZ) Value: (s)
NOTE In a BI-LEVEL PAP mode, the average pressure is the time-weighted average of the measured AIRWAY PRESSURE.		

Table BB.105 defines applicable device settings for each mode of operation.

Table BB.105 – Equipment therapy settings

Parameter	Description	Type
Mode of operation	Device breathing therapy mode as defined within this standard: CPAP, BI-LEVEL PAP (BI-LEVEL POSITIVE AIRWAY PRESSURE), SELF-ADJUSTING positive AIRWAY PRESSURE	Mode selected: (CPAP, BILEVEL, APAP)
SLEEP APNOEA BREATHING THERAPY EQUIPMENT operating in CPAP mode		
CPAP pressure	Delivered pressure setting	Value: (cmH_2O or hPa)
SLEEP APNOEA BREATHING THERAPY EQUIPMENT operating in SELF ADJUSTING positive AIRWAY PRESSURE mode		
Minimum pressure	Minimum delivered pressure setting	Value: (cmH_2O or hPa)
Maximum pressure	Maximum delivered pressure setting	Value: (cmH_2O or hPa)
SLEEP APNOEA BREATHING THERAPY EQUIPMENT operating in BI-LEVEL PAP mode		
Inspiratory pressure	Inspiratory pressure setting	Value: (cmH_2O or hPa)
Expiratory pressure	Expiratory pressure setting	Value: (cmH_2O or hPa)

Table BB.106 defines applicable service and maintenance parameters.

Table BB.106 – Service monitoring

Parameter	Description	Type
Maintenance needed	A MANUFACTURER-specific list of any items requiring maintenance, e.g. filter, MASK, tubing	List of text strings: (MANUFACTURER-defined)
Equipment service indicator	An indication that service is required	Text string: (MANUFACTURER-defined)
Hours of flow generation	Number of hours the equipment has provided flow	Value: (h)

Annex CC
(informative)

Reference to the Essential Principles

This document has been prepared to support the essential principles of safety and performance of a SLEEP APNOEA BREATHING THERAPY EQUIPMENT, its ACCESSORIES or parts as medical devices according to ISO/TR 16142:2006. This document is intended to be acceptable for conformity assessment purposes.

Compliance with this document provides one means of demonstrating conformance with the specific essential principles of ISO/TR 16142:2006. Other means are possible. Table CC.1 maps the clauses and subclauses of this document with the essential principles of ISO/TR 16142:2006.

Table CC.1 — Correspondence between this document and the essential principles (*1 of 2*)

Essential principle of ISO/TR 16142:2006	Corresponding clause(s)/sub-clause(s) of this document	Qualifying remarks/Notes
A.1, A.2, A.3	all	
A.4	201.4, 201.7, 201.15, 201.12.1, 201.102	
A.5	201.4, 201.7, 201.15, 201.12.1, 201.102	
A.6	201.4, 201.7, 201.15, 201.12.1, 201.102	
A.7.1	201.4, 201.7, 201.15, 201.12.1, 201.102	
A.7.2	201.11.6.4, 201.11.6.6	
A.7.3	201.11.6.4, 201.11.6.6	
A.7.4	—	Not applicable
A.7.5	201.11.6.4	
A.7.6	201.11	
A.8.1	201.11.6.6, 201.11.6.7	
A.8.1.1	—	Not applicable
A.8.1.2	—	Not applicable
A.8.2	—	Not applicable
A.8.3	—	Not applicable
A.8.4	—	Not applicable
A.8.5	—	Not addressed
A.8.6	—	Not addressed
A.8.7	201.7.2.17.101	

Table CC.1 — *(2 of 2)*

Essential principle of ISO/TR 16142:2006	Corresponding clause(s)/sub-clause(s) of this document	Qualifying remarks/Notes
A.9.1	201.4.6, 201.7.2.4.101, 201.7.2.13.101, 201.7.2.17.101, 201.7.2.101, 201.7.9.2.2.101, 201.7.9.2.5.101, 201.7.9.2.14.101, 201.12.1.101, 201.12.1.102, 201.12.1.103, 201.12.4.103, 201.16, 201.101, 201.102, 201.103, 211	
A.9.2	201.9, 201.10, 201.11, 201.12, 201.15, 201.17, 202, 206, 208, 211	
A.9.3	201.11	
A.10.1	201.12.4.101	
A.10.2	201.7, 201.12.1, 206	
A.10.3	201.7.4.3	
A.11.1.1	—	Not applicable
A.11.2.1	—	Not applicable
A.11.2.2	—	Not applicable
A.11.3	—	Not applicable
A.11.4	—	Not applicable
A.11.5.1	—	Not applicable
A.11.5.2	—	Not applicable
A.11.5.3	—	Not applicable
A.12.1	201.14	
A.12.2	—	Not applicable
A.12.3	—	Not applicable
A.12.4	—	Not applicable
A.12.5	201.17, 202	
A.12.6	201.8	
A.12.7.1	201.9, 211	
A.12.7.2	201.9	
A.12.7.3	201.9	
A.12.7.4	201.8, 201.15, 201.101, 210.102	
A.12.7.5	201.11	
A.12.8.1	201.12.1	
A.12.8.2	201.12.4	
A.12.8.3	201.7, 201.12.1, 206	
A.13.1	201.7, 201.11.6.4, 201.16	
A.14.1	—	Not addressed

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[3] ISO 10651-3, *Lung ventilators — Part 3: Particular requirements for emergency and transport ventilators*

[4] ISO 10651-4, *Lung ventilators — Part 4: Particular requirements for operator-powered resuscitators*

[5] ISO 10651-6, *Lung ventilators — Part 6: Particular requirements for basic safety and essential performance — Part 6: Home-care ventilatory support devices*

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11) http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5303a1.htm accessed March 15, 2006

Alphabetized index of defined terms used in this particular standard

VERIFICATION (VERIFY) .... IEC 60601-1:2005, 3.138